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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/036,724	03/06/1998	SALDONO FERRONE	FER-1	6300

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	20

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/036,724	Applicant(s) FERRONE ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) *11,12,14-16,19 and 24-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 13, 17-18, 20-23, and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

The Amendment filed August 13, 2002 (Paper No. 19) in response to the Office Action of October 19, 2001 is acknowledged and has been entered.

Claims 1-56 are pending.

Claims 11-12, 14-16, 19, and 24-55 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1-10, 13, 17-18, 20-23, and 56 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

Applicant's assumption that the Examiner meant to consider claims 1-30 and 56 in the first office action is noted. Claims 11-12, 14-16, 19, and 24-55, however, remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species (i.e. Claims 11-12, 14-16, 19, and 24-55) which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Rejections Maintained:

Claims 1-10, 13, 17-18, 20-23, and 56 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention for the reasons of record in Paper No. 14, pages 3-7.

To the extent that applicants have argued against the applicability of each of the cited references (Spitler, Bellone *et al.*, and Gura), such arguments are not found persuasive as the references specifically taught that the nature of the claimed invention combined with the state of the art and relative skill of those in the art is unpredictable, especially with regards to the inhibition of tumor cell growth with reads on the treatment of cancer. Furthermore, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See In re Budnick, 537 F.2d at 538, 190 USPQ at 424; In re Schulze, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); In re Cole, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). Furthermore, as cited in the previous action, the disclosure contained no objective evidence or guidance regarding administration of the immunogen and or a vector that expresses an immunogen in vivo which elicits any immune response. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

As to the clarification of Claim 17, Applicant's respond by saying that the amended claim clarifys that the APC is foreign (Paper No. 19, page 6). However, such clarification does not remedy the rejections for the reasons of record. There is still insufficient guidance and objective

evidence that the method will *predictably* treat an unwanted angiogenic condition wherein the immunogen is expressed on an antigen-presenting cell (APC) that is not native to the mammal. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1-10, 13, 17-18, 20-23, and 56 remain rejected under 35 U.S.C. 112, first paragraph, scope of enablement, for the reasons of record in Paper No. 14, pages 7-8. Applicant's argue (Paper No. 19, page 9) that claim 1 provides for the use of an effective amount of an immunogen that causes an immune response, including native and or foreign immunogens. Applicants argue that since most native immunogens would NOT elicit an immune response in their native hosts, it is "understood" form the specification (pp 9-11) and dependent claim 7, that native immunogens of the invention would need to be modified to improve immunogenicity. This argument has been considered but is not found persuasive. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See Ex parte Oetiker, 23 USPQ2d 1641 (BPAI, 1992). Furthermore, the specification teaches (page 10) that the term "native" means autologous or homologous to an animal. In other words, the native antigens are "self" proteins. Thus, when the antigen is native (Claim 1 is broadly drawn to any immunogen, encompassing native and non-native) it must be modified to improve immunogenicity. Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1-7, 9-10, 13,17, 23, and 56 remain rejected under 35 U.S.C. 102(e) as being anticipated by Nacy *et al.* (U.S. Patent No. 5,919,459) for the reasons of record in Paper No. 14, page 9.

Applicants argue (Paper No. 19, page 10) that Nacy *et al.* is directed to a method for inhibiting "growth factors" in cancer cells and tissues for treating cancer and hyperproliferative diseases. And, unlike the presently claimed application, Nacy *et al.* does not disclose the use of "immunogens" to cause an immune response against any "angiogenic molecule".
This argument has been considered but is not found persuasive because it appears that applicant's are attempting to differentiate the claimed "immunogens" from the circulating "growth factors" of the prior art. However, growth factors like the VEGF protein taught by Nacy *et al.*, are in fact immunogens. According to the specification, "The immunogens of the invention may be *any* angiogenic molecule associated with process of angiogenesis, such as, but not limited to VEGF " (page 9, 2nd paragraph). Thus, the argument that the prior art is "limited to circulating growth factors" is not persuasive. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
November 17, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600